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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
VENCI, DAVID J

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	**Application No.** 10/681,013	**Applicant(s)** KAUVAR ET AL.	
	Examiner David J. Venci	**Art Unit** 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *January 9, 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges Applicants' reply, filed January 9, 2005, which amended claims 1-3. Currently, claims 1-7 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1:

> In line 11, the phrase "the signal generated by said second signal-generating moiety" lacks antecedent basis.
>
> In lines 12-13, the recitation of "which characterizing signal characterizes the label" appears repetitively/gratuitously indefinite in view of anteceding step (a), which recites "a visible characterizing signal that characterizes said label. The identity of additional information, if any, conveyed by "which characterizing signal characterizes the label" is not clear.

In claim 3:

> The phrase "the intensity of the wavelength" is indefinite. Whether/how a "wavelength" possess "intensity is not clear.

Claim Rejections - 35 USC § 102

Claims 1-4 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Nie *et al.* (US 2003/0148544).

Nie *et al.* describes a composition comprising a multiplicity of different labels (see para. [0022], "QD-tagged beads"), wherein each label consists essentially of a particulate support which support is coupled to:

> (a) a first characterizing signal-generating moiety which moiety comprises one or more entities that emit one or more wavelengths that compose a visible signal (see para. [0022], "\ Cross-hatchings"; "X cross-hatchings") (internal quotations omitted); and
>
> (b) a second signal generating moiety consisting of a single fluorophore directly attached to said particulate support which second signal-generating moiety emits the same wavelength at the same intensity from all of said different labels (see para. [0022], "/ cross-hatchings") (internal quotations omitted);
>
> wherein the wavelength of the signal generated by said second signal-generating moiety (see para. [0022], "/ cross-hatchings indicate green quantum dots") (internal quotations omitted) is different from the one or more wavelengths that compose the characterizing signal (see para. [0022], "\ Cross-hatchings indicate red quantum dots"; "X cross-hatchings indicate blue quantum dots") (internal quotations omitted); and
>
> wherein said labels further contains at least one reagent that binds specifically to a target (see para. [0022], "[p]robe oligos").

The following claim language from claim 1 is not afforded patentable weight because the language does not appear to materially structurally alter the composition of claim 1:

> "wherein each different label is directed to a different specific target" (line 2)
> "characterizing" (lines 4, 6 and 12)
> "that characterizes said label" (line 6)
> "which characterizing signal characterizes the label" (line 12-13)

With respect to claim 2, Nie *et al.* describe a composition comprising a multiplicity of different labels, wherein said characterizing signal generating moieties comprise at least two different signal generating entities wherein each of the entities generates a wavelength different from that generated by the other entity(s) and wherein the resulting signal of the labels resulting from said wavelength is varied among the different labels whereby each different label is thereby characterized by a different characterizing signal (see Fig. 1).

With respect to claim 3, Nie *et al.* describe a method to determine the distribution of multiple target substances in a sample which method comprises contacting said sample with the composition of claim 1, wherein the number of labels at a location in the sample is assessed by measuring the intensity of the clamped value signal emitted from the second signal generating moiety (see Fig. 5, para. [0069], "The intensity of the signal generated by the tag attached to the target molecule will be in direct proportion to the amount of target present in the sample").

With respect to claim 4, Nie *et al.* describe a method wherein the sample is displayed on a support suitable for viewing by microscopy (see Fig. 4a).

With respect to claim 7, Nie *et al.* describe a method wherein said particulate supports have diameters of 20-200 nm (see para. [0039]).

Claim Rejections - 35 USC § 103

Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nie *et al.* (US 2003/0148544) is view of Kauvar *et al.* (US 2001/0044116).

Nie *et al.* describe a method for providing a pattern of target substances as substantially described supra. Nie *et al.* do not describe a method wherein the sample comprises intracellular environment or neural circuitry.

However, Kauvar *et al.* disclose a method using microscopy (See Fig. 1) to view intracellular targets (see p. 6, para. (0062], "cell or dendrites"') or neural circuitry (See p. 6, para. (0062], "dendrites"). Therefore, it would have been obvious for a person of ordinary skill in the art to combine the method of contacting an environment to view a pattern of particulate labels of Nie *et al.* with the method of using microscopy to view intracellular targets or neural circuitry of Kauvar *et al.* to provide a method of viewing a pattern of particulate labels in an intracellular or neural circuitry environment. A skilled artisan would have had a reasonable expectation of success in using the labels of Nie *et al.* in a method for viewing an intracellular environment because Nie *et al.* teach that the use of multicolor optical coding using luminescent QDs offers important advantages and applications that are not possible with other types of dyes (see para. [0017]). Nie *et al.* also teach that by using their labels, particulate beads can be quantified based on the observed number of quantum dots, i.e. intensity multiplexing.

Response to Arguments

In prior Office Action, claims 1-7 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants' amendments and/or related argumentation are fully persuasive and sufficient to overcome these rejections. Accordingly, these rejections are withdrawn.

In prior Office Action, claims 1-4 and 7 were rejected under 35 U.S.C. 102(e) as being anticipated by Nie *et al.* (US 2003/0148544). In addition, claims 5-6 were rejected under 35 U.S.C. 103(a) as being unpatentable over Nie *et al.* (US 2003/0148544) is view of Kauvar *et al.* (US 2001/0044116). In response, Applicants amend independent claim 1 to add, *inter alia*, the limitation of a second signal-generating moiety "consisting of a single fluorophore". Applicants argue that "[t]he present invention excludes the possibility that the second signal generating moiety... could include a [additional] quencher – an essential element of the Nie system" (see Applicants' reply, paragraph bridging pp. 6-7) (paraphrasing mine). Applicants' amendment and related argumentation have been carefully considered but are not sufficient to overcome these rejections. In Fig. 5, Nie *et al.* appear to describe a second signal generating moiety consisting of a single fluorophore which emits the same wavelength at the same intensity from all of said different labels (see para. [0022], "/ cross-hatchings") (internal quotations omitted). This single fluorophore appears to fall within the scope of Applicants' amended claim 1 requiring a second signal-generating moiety "consisting of a single fluorophore". Thus, Nie *et al.* continue to anticipate Applicants' invention, as claimed.

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci
Examiner
Art Unit 1641

djv

LONG V. LE
SUPERVISORY PATENT EXAMINER
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04/14/06